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| U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS | | REVIEW DATE 3/23/01 | NAME OF FOREIGN LABORATORY Foedevareregion Aarhus Laboratory |
| FOREIGN COUNTRY LABORATORY REVIEW | | | |
| FOREIGN GOV'T AGENCY Danish Veterinary and Food Administration | | CITY & COUNTRY Aarhus, Denmark | ADDRESS OF LABORATORY Goeteborgallee 1 |
| NAME OF REVIEWER Dr. Gary D. Bolstad | | NAME OF FOREIGN OFFICIAL Dr. Jens Munk Ebbesen; Dr. Inge Emborg | |

| Residue Code/Name | | | OC | pcb | TE | | | | | | | | | | | | | | |
|------------------------------|------------------------------|--------|-----------------|-----|----|------|--|--|--|--|--|--|--|--|--|--|--|--|--|
| SAMPLING PROCEDURES | REVIEW ITEMS | ITEM # | EVALUATION CODE | | | | | | | | | | | | | | | | |
| | Sample Handling | 01 | | A | A | A | | | | | | | | | | | | | |
| | Sampling Frequency | 02 | | C | C | C | | | | | | | | | | | | | |
| | Timely Analyses | 03 | | A | A | A | | | | | | | | | | | | | |
| | Compositing Procedure | 04 | | O | O | O | | | | | | | | | | | | | |
| | Interpret Comp Data | 05 | | O | O | O | | | | | | | | | | | | | |
| | Data Reporting | 06 | | A | A | A | | | | | | | | | | | | | |
| ANALYTICAL PROCEDURES | Acceptable Method | 07 | EVALUATION CODE | A | A | A | | | | | | | | | | | | | |
| | Correct Tissue(s) | 08 | | A | A | Musc | | | | | | | | | | | | | |
| | Equipment Operation | 09 | | A | A | A | | | | | | | | | | | | | |
| | Instrument Printouts | 10 | | A | A | A | | | | | | | | | | | | | |
| QUALITY ASSURANCE PROCEDURES | Minimum Detection Levels | 11 | EVALUATION CODE | A | A | A | | | | | | | | | | | | | |
| | Recovery Frequency | 12 | | A | A | A | | | | | | | | | | | | | |
| | Percent Recovery | 13 | | A | A | A | | | | | | | | | | | | | |
| | Check Sample Frequency | 14 | | C | C | C | | | | | | | | | | | | | |
| | All analyst w/Check Samples | 15 | | A | A | A | | | | | | | | | | | | | |
| | Corrective Actions | 16 | | A | A | A | | | | | | | | | | | | | |
| | International Check Samples | 17 | | A | A | A | | | | | | | | | | | | | |
| REVIEW PROCEDURES | Corrected Prior Deficiencies | 18 | EVAL. CODE | C | C | O | | | | | | | | | | | | | |
| OTHER REVIEW | | 19 | EVAL. CODE | | | | | | | | | | | | | | | | |
| | | 20 | EVAL. CODE | | | | | | | | | | | | | | | | |

SIGNATURE OF REVIEWER

JD Bolstad

DATE

3/23/01

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|--|-------------|---|--|
| FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i> | | REVIEW DATE 3/23/01 | NAME OF FOREIGN LABORATORY Foedevareregion Aarhus Laboratory |
| FOREIGN GOV'T AGENCY Danish Veterinary and Food Administration | | CITY & COUNTRY Aarhus, Denmark | ADDRESS OF LABORATORY Goeteborgallee 1 |
| NAME OF REVIEWER Dr. Gary D. Bolstad | | NAME OF FOREIGN OFFICIAL Dr. Jens Munk Ebbesen; Dr. Inge Emborg | |
| RESIDUE | ITEM | COMMENTS | |
| OC,PCB | 2 | A new method for organochlorine pesticides and PCBs had just recently been developed, and the sampling requests had just been distributed at the end of February. Note: all the planned analyses for CY 2000 had been completed. | |
| TE | 2 | The sampling for trace elements was just getting underway. Previously two other labs were also performing the analyses for these; this laboratory will now undertake the entire country's testing for traced elements. Note: Arsenic was not part of the sampling plan at the moment; new equipment was acquired 5 months previously and optimization was still ongoing. Current sampling was for lead, mercury, cadmium, and selenium. | |
| All | 14 | <p>Intra-laboratory check samples were not being performed in this laboratory. International check samples were provided by FAPAS in England and had been performed in April and October 2000 for organochlorines and were scheduled for June and October 2001; the schedule also called for two check samples each for trace elements for April, July, and November 2001.</p> <p>The quality control system did not include the documentation of the preparation of fresh standard solutions in a bound notebook with previously numbered pages.</p> | |



Microbiology Laboratory Audit—March 19, 2001
Auditor: Dr. Gary D. Bolstad

General

Name & location of lab: Laboratory of Fødevareregion Sønderjylland, Haderslev, Denmark

Private or gov't lab? Government

How & when was accreditation obtained? First accredited in October 1993 by Danish Accreditation

How & how often is accreditation maintained? Accreditation criteria are reviewed every 15 months and accreditation is renewed with a full review every 5 years.

When and how is payment for analysis provided? Payment is made by the establishments; they are billed monthly.

Are results released before payment is received? Yes

What are the qualifications of the analyst(s) performing the individual tasks within a method?
The laboratory technicians have all received formal education including specific courses in laboratory technology for 2½ years; this includes one year of OJT. They also participate in continuing education courses every year.

What are the qualifications of the direct supervisor of the analysts? Both have Masters degrees in biology and biochemistry; one has additional advanced training in microbiology.

Methodology for HACCP Salmonella samples (regulatory labs)

Does this lab analyze HACCP Salmonella samples? Routine *Salmonella* testing in Denmark, within the framework of the Pathogen Reduction requirements, is done by the establishments, under DVFA supervision. These field samples are analyzed in several private laboratories in the country. DVFA personnel also take one sample per week in each establishment certified to export to the U.S.; these samples are analyzed in government laboratories; these are verification samples, to verify that the establishments' results are accurate and valid. This audit was performed at one of the government laboratories performing the verification analysis for the region of Sønderjylland.

How are HACCP Salmonella samples received & recorded?. (See above.) They come by express mail with guaranteed next-day delivery; the transit temperature is logged.

Are HACCP Salmonella samples analyzed on the day of receipt? (See above.) Yes

What method(s) is used for HACCP Salmonella samples? NMKL-71 (Nordic Committee on Food Analysis)

Is it a qualitative method (i.e. +/- result)? Yes

Are HACCP ground beef samples analyzed for Salmonella? Yes

What is the size of the ground beef test portion? 25 grams

What buffer (and what volume) is used for:

Sponge samples for Salmonella? BPW

Poultry rinsates for Salmonella? N?A

Salmonella ground beef sample homogenates? 25 gm meat + 225 ml BPW

What is the formulation of the Buffered Peptone Water you use?

| | |
|--------------------------------|----------|
| Peptone | 10.0 g/l |
| NaCl | 5.0 " |
| Disodium phosphate | 3.5 " |
| Potassium dihydrogen phosphate | 1.5 " |
| pH 7.2 ± 0.2 | |

What analytical controls are used for Salmonella analyses (i.e. control cultures, etc.)? Both a positive control and a sterile control.

Are they employed for each sample set? Yes

How are HACCP Salmonella results expressed? Detected or Not Detected

How are HACCP Salmonella results recorded?: On a certificate which the lab sends to the Veterinarian-In-Charge in the establishment of origin. A copy is kept at the lab.

How and to whom are HACCP Salmonella results reported? A copy of Not-Detected results is sent to the Veterinarian-In-Charge at the establishment of origin; another copy is kept at the regional DVFA-HQ, which houses the government lab.

Are "check" samples periodically used to test the proficiency of the lab and analysts for Salmonella testing?

1. For individual analysts or for the lab as a whole? No—the last was in November-December 1998 (S. adabraka is used as a positive control with each sample set.)
2. What species/strains are used? See above
3. How many samples are analyzed and how often? See above
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing?. See above
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts?. See above

Methodology for HACCP generic E. coli samples (in-plant or other private labs)

Does this lab analyze HACCP generic E. coli samples? No



Microbiology Laboratory Audit—March 22, 2001
Auditor: Dr. Gary D. Bolstad

General

Name & location of lab: Danish Crown, Horsens Dept.; Horsens, Denmark

Private or gov't lab? Private. The DVFA officials monitor the operations in the laboratory, including sample receipt from other establishments, daily and also the taking of samples in the establishment. Each week the DVFA officials also take one swab sample and have it analyzed for *Salmonella* in an accredited laboratory in Vejle, some 25 km distant.

How & when was accreditation obtained? Not accredited. Approved by Danish Veterinary and Food Authority.

How & how often is accreditation maintained? See above.

When and how is payment for analysis provided? This laboratory is one of three situated in Danish Crown (DC) establishments, and this lab analyzes samples from other DC plants as well as from its own production. The analyses are paid for by the Danish Crown mother company.

Are results released before payment is received? See above.

What are the qualifications of the analyst(s) performing the individual tasks within a method? All have completed specific courses in laboratory technology.

What are the qualifications of the direct supervisor of the analysts? Has completed specific courses in laboratory technology.

Methodology for HACCP Salmonella samples (regulatory labs)

Does this lab analyze HACCP Salmonella samples? Yes.

How are HACCP Salmonella samples received & recorded? They arrive by express mail, and arrive within one day of sending.

Are HACCP Salmonella samples analyzed on the day of receipt? Yes.

What method(s) is used for HACCP Salmonella samples? Either NMKL-71 (Nordic Committee on Food Analysis) or EIAFOSS (Elisa quick-test) (The latter is more expensive but faster, and is used when more rapid results are desired.)

Is it a qualitative method (i.e. +/- result)? Yes.

Are HACCP ground beef samples analyzed for Salmonella? No.

What is the size of the ground beef test portion? N/A

What buffer (and what volume) is used for:

Sponge samples for Salmonella? 10 ml Buffered Peptone Water; 15 ml more are added in the laboratory.

Poultry rinsates for Salmonella? N/A

Salmonella ground beef sample homogenates? N/A

What is the formulation of the Buffered Peptone Water you use?

| | |
|------------------|----------|
| Peptone | 10.0 g/l |
| NaCl | 5.0 " |
| Phosphate buffer | 10.5 |

25.5 g of the above diluted to 1 liter; pH 7.2 ± 0.2

What analytical controls are used for Salmonella analyses (i.e. control cultures, etc.)? S. adabraka

Are they employed for each sample set? Yes.

How are HACCP Salmonella results expressed? Detected / not detected

How are HACCP Salmonella results recorded?: The results are listed in a table.

How and to whom are HACCP Salmonella results reported? (1) the establishment management, (2) the DVFA Veterinarian-In-Charge in the establishments, by mail. In the event of positive samples, they are notified by telephone.

Are "check" samples periodically used to test the proficiency of the lab and analysts for Salmonella testing?

1. For individual analysts or for the lab as a whole? For the lab as a whole.
2. What species/strains are used? Samples are provided by the official government laboratory in Ringsted; strains that have been employed are *S. amsterdam* and *pomona*.
3. How many samples are analyzed and how often?. Once per year.
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? Samples have contained *Salmonella* spp., *Yersinia*, *Pseudomonas*, *Streptococcus*, *Staphylococcus*, *Listeria*, *Citrobacter* and *Lactobacillus*.
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts? Will provide.

Methodology for HACCP generic *E. coli* samples (in-plant or other private labs)

Does this lab analyze HACCP generic *E. coli* samples? Yes

How are HACCP *E. coli* samples received & recorded? Same as for *Salmonella*

Are HACCP *E. coli* samples analyzed on the day of receipt? Yes

What method is used for HACCP generic *E. coli* samples? NMLK (see above); 3M Petrifilm

Is it a quantitative method? Yes

What buffer (and what volume) is used for:

E. coli sponge samples? 0.9% physiological saline solution, 10 ml; 15 ml are added when received at the lab.

Poultry rinsates for generic E. coli? N/A

What analytical controls are used? No positive controls are used

Are they employed for each sample set? No controls: Petrifilm is used

How are HACCP E. coli results calculated and/or expressed? CFU/cm²

How are E. coli results recorded:

Data sheets/work sheets? Both in table form and on graphs.

Log books?

How and to whom are HACCP E. coli results reported? (1) the establishment management, (2) the DVFA Veterinarian-In-Charge in the establishments

Are "check" samples periodically used to test the proficiency of the lab and analysts for generic E. coli testing? Yes

1. *For individual analysts or for the lab as a whole?* For the lab as a whole.
2. *What species/strains are used?* Samples have contained an *E. coli* strain from Microbiologics, Cat. Nr. 0483s, St. Cloud, MN, 96303, and also *Salmonella spp.*, *Yersinia*, *Pseudomonas*, *Streptococcus*, *Staphylococcus*, *Listeria*, *Citrobacter* and *Lactobacillus*.
3. *How many samples are analyzed and how often?* Once per year
6. 4. *Are both inoculated and uninoculated samples provided to analysts for the proficiency testing?* Yes.
5. *How many colony-forming units (CFU) per gram are inoculated into the proficiency samples provided to analysts?* 1,000 CFU per gram.



Microbiology Laboratory Audit—April 6, 2001
Auditor: Dr. Gary D. Bolstad

General

Name & location of lab: Danish Crown Saeby; Saeby, Denmark

Private or gov't lab? The DVFA officials monitor the operations in the laboratory, including sample receipt from other establishments, daily and also the taking of samples in the establishment. Each week the DVFA officials also take one swab sample and have it analyzed for *Salmonella* in an accredited laboratory in Aalborg, some 50 km distant.

How & when was accreditation obtained? Not accredited

How & how often is accreditation maintained? See above

When and how is payment for analysis provided? This laboratory is one of three situated in Danish Crown (DC) establishments, and this lab analyzes samples from other DC plants as well as from its own production. The analyses are paid for by the Danish Crown mother company.

Are results released before payment is received? See above.

What are the qualifications of the analyst(s) performing the individual tasks within a method?
All have completed specific courses in laboratory technology.

What are the qualifications of the direct supervisor of the analysts? Has completed specific courses in laboratory technology.

Methodology for HACCP Salmonella samples (regulatory labs)

Does this lab analyze HACCP Salmonella samples? Yes.

How are HACCP Salmonella samples received & recorded? They arrive by express mail, and arrive within one day of sending.

Are HACCP Salmonella samples analyzed on the day of receipt? Yes.

What method(s) is used for HACCP Salmonella samples?

Is it a qualitative method (i.e. +/- result)? Yes.

Are HACCP ground beef samples analyzed for Salmonella? No.

What is the size of the ground beef test portion? See above.

What buffer (and what volume) is used for:

Sponge samples for Salmonella? 10 ml Buffered Peptone Water; 15 ml more are added in the laboratory.

Poultry rinsates for *Salmonella*? N/A

Salmonella ground beef sample homogenates? N/A

What is the formulation of the Buffered Peptone Water you use?

| | |
|--------------------------------|----------|
| Peptone | 10.0 g/l |
| NaCl | 5.0 " |
| Disodium phosphate | 3.5 " |
| Potassium dihydrogen phosphate | 1.5 " |
| pH 7.2 ± 0.2 | |

What analytical controls are used for *Salmonella* analyses (i.e. control cultures, etc.)? *S. adabraka*

Are they employed for each sample set? Yes.

How are HACCP *Salmonella* results expressed? Detected / not detected

How are HACCP *Salmonella* results recorded? The results are listed in a table.

How and to whom are HACCP *Salmonella* results reported? (1) the establishment management, (2) the DVFA Veterinarian-In-Charge in the establishments, by mail. In the event of positive samples, they are notified by telephone.

Are "check" samples periodically used to test the proficiency of the lab and analysts for *Salmonella* testing?

1. For individual analysts or for the lab as a whole? For the lab as a whole.
2. What species/strains are used? Samples are provided by the official government laboratory in Ringsted; strains that have been employed are *S. amsterdam* and *pomona*.
3. How many samples are analyzed and how often?. Once per year.
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? Samples have contained *Salmonella* spp., *Yersinia*, *Pseudomonas*, *Streptococcus*, *Staphylococcus*, *Listeria*, *Citrobacter* and *Lactobacillus*.
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts? Will provide.

Methodology for HACCP generic *E. coli* samples (in-plant or other private labs)

Does this lab analyze HACCP generic *E. coli* samples? Yes

How are HACCP *E. coli* samples received & recorded? Same as for *Salmonella*

Are HACCP *E. coli* samples analyzed on the day of receipt? Yes

What method is used for HACCP generic *E. coli* samples? NMLK (see above); 3M Petrifilm

Is it a quantitative method? Yes

What buffer (and what volume) is used for:

E. coli sponge samples? 0.9% physiological saline solution, 10 ml; 15 ml are added when received at the lab.

Poultry rinsates for generic E. coli? N/A

What analytical controls are used? No positive controls are used

Are they employed for each sample set? No controls: Petrifilm is used

How are HACCP E. coli results calculated and/or expressed? CFU/cm²

How are E. coli results recorded:

Data sheets/work sheets? Both in table form and on graphs.

Log books?

How and to whom are HACCP E. coli results reported? By mail, to (1) the establishment management, (2) the DVFA Veterinarian-In-Charge in the establishments

Are "check" samples periodically used to test the proficiency of the lab and analysts for generic E. coli testing? Yes

1. *For individual analysts or for the lab as a whole?* For the lab as a whole.
2. *What species/strains are used?* Samples have contained *E. coli* VDL 228, *Salmonella* spp., *Yersinia*, *Pseudomonas*, *Streptococcus*, *Staphylococcus*, *Listeria*, *Citrobacter* and *Lactobacillus*.
3. *How many samples are analyzed and how often?* Once per year
6. 4. *Are both inoculated and uninoculated samples provided to analysts for the proficiency testing?* Yes.
5. *How many colony-forming units (CFU) per gram are inoculated into the proficiency samples provided to analysts?* 1,000 CFU per gram.